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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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10/714,068

11/14/2003

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EXAMINER

QIAN, CELINE X

ART UNIT

PAPER NUMBER

1636

MAIL DATE

DELIVERY MODE

07/21/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/714,068 | YANG ET AL. | |
| | Examiner | Art Unit | |
| | CELINE X. QIAN | 1636 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 April 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 37, 39 and 40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 37, 39 and 40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 November 2003 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 37, 39 and 40 are pending in the application.

This Office Action is in response to the Amendment filed on 4/23/08.

Response to Amendment

The rejection of claim 37 under 35 U.S.C.102 (b) has been withdrawn in light of the amendment.

The rejection of claims 39 and 40 under 35 U.S.C. 103 (a) has been withdrawn in light of the amendment.

New Grounds of Rejection Necessitated by Amendment

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 37 is rejected under 35 U.S.C. 103(a) as being unpatentable over Link et al (Cell Stress & Chaperones, 1999. Vol.4, No. 4, pages 235-242).

Link et al. teach transgenic *C. elegans* expressing jellyfish GFP under the control of the promoter for the inducible small heat shock protein gene hsp-16-2 (see page 238, bridging paragraph). Link et al. teach that the expression of GFP parallels the endogenous expression of hsp-16 gene, and allows for direct visualization, localization, and quantitation of hsp-16 expression in living animals (see Figure 1 and legend). Link et al. also teach applying a variety of stress signals including quinones, and expression of the human β amyloid, specifically induces the reporter production (see Figure 2 and legend). However, Link et al. do not teach whether the *C. elegans* is mobile when fluorescence is observed.

Although the Link reference does not explicitly state that the *C. elegans* is mobile under the fluorescent microscope, Link et al. does indicate that they are live animals in which they are subject to repeated heat shock treatment in between the imaging (see legend of Figure 1, section B). While an ordinary skill in the art would realize that it is in the best interest for a good quality photo to be taken while the animal is not moving, the ordinary skill in the art would also recognize that the animal also have the ability to be mobile because they are still alive. In other words, the claimed method would have been obvious in view of the teaching of the Link et al. because Link et al. have taught every step of the claimed method. It would have been obvious to an ordinary artisan that the expression of the promoter through whole body optical imaging may be detected while the *C. elegans* is mobile, and recording such mobility may be achieved through real time video instead of photograph, which cannot record the mobility of the *C. elegans*.

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Therefore, the claimed invention would have been *prima facie* obvious at the time the invention was made.

Claims 39 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Link et al., in view of Lin et al.

The teaching of Link et al. was discussed above. However, Link et al. do not teach administering a mutation inducing agent or treatment to the laboratory animal.

Lin et al. teach method of identify compounds that affect expression of the genes by using transgenic zebra fish comprising a promoter from an endogenous gene, for example, GATA1, linked to GFP (see col.11, lines 62-64, and last paragraph of col.10 to 1st paragraph of col.11). Lin et al. teach that the test compounds can be administered to the transgenic fish to assess the compound on the expression of gene of interest, and comparing the expression to a control zebra fish such that the effect of the compound can be determined (see bridging col. of 10-11). Lin et al. further teach method of identifying genes that affect the expression of fish genes by using transgenic fish carrying the construct of comprising a promoter of a fish gene and a reporter gene, comprising introducing the mutation into the transgenic fish and comparing the expression of the reporter gene to a fish without the mutation (see col. 11, lines 10-18). Moreover, Lin et al. teach that chemical mutagenesis in zebra fish genome generated more than one thousand different mutants with defects in developmental processes (See col. 11, lines 16-29).

The obviousness of the C.elegan for being mobile was discussed above. Both Link and Lin et al. teach using multi-cellular organism comprising a construct that comprises a promoter from an endogenous gene operably linked to a reporter protein, such as GFP for identifying

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expression modulators or test compounds that affect the expression of the endogenous gene.

This teaching reflects that it is well known at the time of filing to use transgenic or chimeric laboratory animal such as zebrafish and *C. elegans* that comprises a construct containing a promoter from an endogenous gene linked to a reporter to identify test compounds that affect the expression of the endogenous gene. Both Link and Lin et al. teach the use of GFP as reporter, indicating it is a commonly used reporter. Link et al. further teach that the fluorescent generated from GFP may be detected by external imaging. While Link et al. does not teach administering a mutation inducing agent that affect the expression of an endogenous promoter, Lin et al. suggested that the transgenic fish carrying the reporter may be used to detect mutation that affect the expression of the promoter, and further taught chemical mutagenesis that results in mutation of the gene. By looking at the teaching as a whole, it would have been obvious to one of ordinary skill in the art to use mutation inducing agent or treatment to induce mutation in a laboratory animal that carries the construct with a reporter gene and a promoter of interest, and determine whether the mutation affect the promoter expression by measuring the reporter gene expression. One of ordinary skill in the art would use external imaging to detect the fluorescent to detect such expression since it is taught by Link et al. and such procedure would be able to record real time measurement, and is non-invasive. As demonstrated by Link et al., heat shock treatment, quinone treatment alters the expression of the GFP, and is detectable by external whole body imaging. As such, applying a mutation inducing compound to a system such as the one taught by Link et al. and detecting the fluorescent light by whole body optical imaging would yield predictable result. Applying known techniques to a system to yield predictable results is obvious

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to one of ordinary skill of art. Therefore, the claimed invention would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CELINE X. QIAN whose telephone number is (571)272-0777. The examiner can normally be reached on 10-6:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joe Woitach Ph.D. can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Celine X Qian Ph.D./
Primary Examiner, Art Unit 1636